# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Choi et al. Docket No.: PB340P2

Patent No : 7.056.510

Issued: June 6, 2006

Application No.: 08/961,083

Filed: October 30, 1997

Confirmation No.: 6931

Art Unit: 1645

Examiner: J. A. Hines

For: Streptococcus pneumoniae SP036 Polynucleotides, Polypeptides, Antigens and

Vaccines

Vaccines

# APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d) AND PETITION UNDER 37 C.F.R. § 1.181(a)(3)

MS Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) indicated on the face of U.S. Patent No. 7,056,510 (the '510 Patent). Patentees believe the correct PTA is at least 942 days, not 0 days as indicated on the face of the '510 Patent. This application is made pursuant to 37 C.F.R. § 1.705(d) because the '510 Patent should have indicated a revised PTA. This application is being filed within two months of the date of issue of the '510 Patent, and therefore is timely made. The requirements of 37 C.F.R. § 1.705(d) have been satisfied, as the fee required by 37 C.F.R. § 1.705(b)(1) has been paid herewith, and the requirements of 37 C.F.R. § 1.705(b)(2) are satisfied by the following Statement of Facts as supplemented by the attached Exhibit.

To the extent necessary, in conjunction with the instant Application for Patent Term Adjustment, Patentees also respectfully petition to invoke the supervisory authority of the Director under 37 C.F.R. § 1.181(a)(3) to correct the PTA previously accorded the '510 Patent under 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. § 1.705(b). More particularly, despite the decision of January 3, 2005 granting Patentees' Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(b) filed July 29, 2004 (which accorded Patentees 388

days of PTA as of the mailing of the Notice of Allowance), the face of the '510 Patent indicates a PTA of 0 days. Moreover, the online PAIR entry for the '510 Patent does not even contain a PTA section, which should be present regardless of the amount of PTA accorded. Thus, as the prior decision of January 3, 2005 has not been given effect by the appropriate staff at the PTO, Patentees respectfully request that the Director or his designees exercise their supervisory authority to correct these errors in the PTA, as supplemented by any PTA accorded Patentees pursuant to the instant Application for PTA under 37 C.F.R. § 1.705(d).

#### STATEMENT OF FACTS

## Eligibility for PTA

 As acknowledged by the PTO in the Decision on Application for Patent Term Adjustment mailed January 3, 2005 (attached as Exhibit A), the '510 Patent is eligible for patent term adjustment under 35 U.S.C. § 154 because a CPA was filed and entered by the Office on December 11, 2000.

## Correct PTA, Bases Therefor, and Relevant Dates

- The correct PTA for the '510 Patent under 35 U.S.C. § 154(b) is at least 942 days as explained in more detail below.
- 3. As agreed by the Office in the Decision on Application for Patent Term Adjustment mailed January 3, 2005, the '510 Patent is entitled to 388 days of PTA under 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. § 1.702(a)(1). See Exhibit A. Despite this Decision, the face of the '510 Patent indicates a PTA of 0 days, and the online PAIR entry for the '510 Patent does not even contain a PTA section.
- 4. In addition to the PTA noted in paragraph 3 above, the '510 Patent is also entitled to 554 additional days of PTA under 35 U.S.C. § 154(b)(1)(A)(iv) and 37 C.F.R. § 1.702(a)(4), as the PTO failed to issue the '510 Patent within 4 months after the date the issue fee was paid under 35 U.S.C. § 151 and all outstanding requirements were satisfied. More particularly, the issue fee was paid on July 29, 2004, and the '510 Patent issued on

June 6, 2006. Thus, the period noted in 37 C.F.R. § 1.703(a)(6) between the day after the date that is four months after the issue fee was paid and all outstanding requirements were satisfied (November 30, 2004) and the date the '510 Patent was issued (June 6, 2006) is 554 days.

- 5. Moreover, the '510 Patent is also entitled to 908 days of PTA under 35 U.S.C. § 1.54(b)(1)(B) and 37 C.F.R. § 1.702(b), as the PTO failed to issue the '510 Patent within three years of the filing date of the application under 35 U.S.C. § 1.111(a). More particularly, as acknowledged by the PTO in the Decision on Application for Patent Term Adjustment mailed January 3, 2005 (Exhibit A), a continuing prosecution application (CPA) was filed on December 11, 2000, yet the '510 Patent did not issue until June 6, 2006. Thus, the period noted in 37 C.F.R. § 1.703(b) between the day after the date that is three years after the date on which the application was filed under 35 U.S.C. § 1.111(a) (December 12, 2003) and the date the '510 Patent was issued (June 6, 2006) is 908 days.
- 6. It is Patentees' understanding that pursuant to 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f), the PTO would consider the 908 days of PTA under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) described in paragraph 5 above to overlap with the 942 days of PTA under 35 U.S.C. § 154(b)(1)(A)(i)&(iv) and 37 C.F.R. § 1.702(a)(1) & (4) described in paragraphs 2-4 above. Assuming this to be correct, if the PTO accords the '510 Patent the 942 days of PTA described in paragraphs 2-4, then the '510 Patent would not be entitled to any of the 908 days of PTA described in paragraph 5. However, if the PTO does not grant the instant Application for PTA with respect to paragraph 4, then the '510 Patent would be entitled to 520 days of non-overlapping PTA described in paragraph 5, in addition to the 388 days of PTA described in paragraph 3, for a total of 908 days. Moreover, if the PTO's position as to overlap or Patentees' understanding of that position is incorrect, then the '510 Patent would be entitled to 388 days of PTA described in paragraph 3, 554 days of PTA described in paragraph 4, and an additional 354 days of the PTA described in paragraph 5 (the non-overlapping period between December 12, 2003 and November 29, 2004), for a total of 1296 days.

#### Terminal Disclaimer

The instant application is not subject to a terminal disclaimer.

## Efforts to Conclude Processing or Examination

- 8. As acknowledged by the PTO in the Decision on Application for Patent Term Adjustment mailed January 3, 2005 (Exhibit A), as of the mailing of the Notice of Allowance on May 21, 2004, Patentees had not failed to engage in reasonable efforts to conclude prosecution or examination within the meaning of § 1.704.
- Since May 21, 2004, there were no circumstances that could reasonably be construed as a failure of Patentees to engage in reasonable efforts to conclude processing or examination of the '510 Patent within the meaning of § 1.704.

### CONCLUSION

Patentees respectfully request that the PTA for the '510 Patent be reconsidered in light of the facts and circumstances described above. In particular, Patentees maintain that the '510 Patent is entitled to at least 942 days of PTA. To the extent necessary, Patentees also respectfully request that the Director or his designees exercise their supervisory authority to correct the above-noted errors in the PTA, as supplemented by any PTA accorded Patentees pursuant to the instant Application for PTA under 37 C.F.R. § 1.705(d), in light of the fact that the prior decision of January 3, 2005 has not been given effect by the appropriate staff at the PTO.

If any further information is required, please contact the undersigned at the number listed below. Please charge any additional fees due in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

Dated: August 4, 2006

Respectfully submitted,

Mark J. Hyman

Registration No.: 46,789 HUMAN GENOME SCIENCES, INC. Intellectual Property Dept. 14200 Shady Grove Road Rockville, Maryland 20850 (240) 314-1224

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Paper No.

HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE MD 20850

COPY MAILED

JAN 3 2005

OFFICE OF PETITIONS

In re Application of Choi et al. Application No. 08/961,083 Filed: October 30, 1997 Atty Docket No. PB340P2

DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)," filed July 29, 2004. Applicants request correction of an entry of a calculation of patent term extension of zero (0) days to an entry of an initial determination of patent term adjustment (PTA) under 35 U.S.C. 154(b)(3)(i) of three hundred eighty-eight (388) days.

The application for patent term adjustment is **GRANTED**.

The Office has updated the PAIR screen to reflect that the correct Patent Term Adjustment (PTA) determination at the time of the mailing of the Notice of Allowance is three hundred eighty-eight (388) days. A copy of the updated PAIR screen, showing the correct determination, is enclosed.

On May 21, 2004, the Office mailed a Determination of Patent Term Extension under 35 U.S.C. 154(b) in the above-identified application. The Notice stated that the patent term extension (PTE) to date is 0 days.

On July 29, 2004, applicants timely submitted an application for patent term adjustment, asserting that the application became subject to the provisions providing for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 by virtue of the filing of a continuing prosecution application (CPA) on December 11, 2000. Furthermore, applicants assert entitlement to a patent term adjustment on the basis that the USPTO failed to mail a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 within fourteen months of the filing date of the application. Specifically, applicants

The Issue Fee payment was also received in the Office on July 29, 2004.

contend entitlement to a patent term adjustment at the time of mailing of the Notice of Allowance of three hundred eighty-eight (388) days, the number of days in the period beginning on the day after the date that is fourteen months after the date on which the CPA was filed, which is February 11, 2002, and ending on the date of mailing of a restriction requirement on March 6, 2003.

Applicants state that the patent issuing from this application is not subject to any terminal disclaimer. Applicants further state that they have not engaged in any circumstance during the prosecution of the application which constitutes a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 CFR § 1.704.

Applicants' arguments are well-taken. A review of the application history reveals that the application became eligible for patent term adjustment by virtue of the filing of a CPA on December 11, 2000. A review of the application history also confirms that, as of the time of mailing of the Notice of Allowance, applicants have correctly set forth the basis for adjustment pursuant to 37 C.F.R. § 1.702(a)(1) and the period of adjustment.

Moreover, applicants' filings have been carefully reviewed. It has been determined that, as of the mailing of the Notice of Allowance, applicants had not failed to engage in reasonable efforts to conclude prosecution or examination within the meaning of § 1.704.

In view thereof, the correct determination of patent term adjustment at the time of the mailing of the Notice of Allowance is three hundred eighty-eight (388) days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The application file is being forwarded to the Publishing Division for processing into a patent.

Telephone inquiries specific to this matter should be directed to Nancy Johnson, Senior Petitions Attorney, at (571) 272-3219.

Kery A Fue

Karin Ferriter Senior Legal Advisor Office of Patent Legal Administration Office of Deputy Commissioner

for Patent Examination Policy

Enclosure: Copy of Revised PAIR Screen